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Drug Action
West Bengal

A short biodat

Though the record of sporadic groups all over through came in the movement in 198 tremendous public Health and Health gaining ground to being individual's needing political being realised that siv domain of the feeble voice of a few of the medical people up by peoples organisations

A few doctor representatives, scientists met on 8th April 1984 and realised that the 'Drug Issue' is one of the most pressing matter of health care, organised Drug Action Forum, West Bengal. Forum's viewpoints and objects were described to a host of individual and organisations who responded warmly and with encouraging fervour. Infact, Forum's tasks have now been taken up by all those people and the Forum has now come to be established as the platform of all persons and organisations who are concerned with the Drug Problem and intend to act in this field.

During the last 9 months the Forum has

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Transnational Drug Companies. The booklet has received a remarkable appreciation from the people and the Forum has been flooded with a demand for the publication of more information in this matter. The Forum will shortly publish its second booklet detailing relevant facts on unscientific and harmful drugs.

In July 1984, the Forum joined with other organisations working on the Drug problem in different states of India and organised the "All India Drug Action Network" (AIDAN). AIDAN will launch an All India Campaign on

the objectives of the Forum shortly. The Forum has also established international connection with various organisations working on the Drug issue particularly 'Health Action International' and "Ganaswasthya Kendra" of Bangladesh.

The Forum believes that a peoples' movement is the need of the hour to persuade the authorities to adopt a Rational Drug Policy for the Country so that all Citizens, irrespective of their purchasing power, receive essential drugs to escape from avoidable disease, disability and death. The Forum hopes that all responsible and socially conscious citizens will share this belief and lead their efforts to achieve its objectives.

● **Organisations who took up the Cause of Drug Action Forum**

All West Bengal Sales Representatives Union
Arabinda Sangha, Tollygunge
Association for the Protection of Democratic Rights
Barrackpur Science and Cultural Association
Bejoypur Town Club, Sodepur
Bijnan Darbar, Kanchrapara
Bodhichakra, Ballygunge
Calcutta Socio-Cultural Organisation
Centre for Science and Society, Jadavpur
Chinsurah Science Club, Hooghly
Consumers' Action Forum, Calcutta
Dwarakanath Kotnis Memorial Committee, W.B.

Federation of Medical Representatives Associations of India
Ganabijnan Samannaya Kendra, W. B.
Ganasamskriti Sanstha, Panihati
Ganabijnan Parsad, Kuntighat
Health Services Association, W. B.
Indian Medical Association, Bengal State Branch
Indian Peoples' Welfare Society, Jhargram
Gem Coaching, Baghajatin
Khatra Science Club, Bankura
Manas, Park Circus
My People, Paikpara
Madhya Kalikata Janaswasthya Kendra
Peoples Science Forum, Durgapur
Prasenjit Memorial Community Health Centre, Beliaghata
R. G. Kar Medical College Students' Union, Calcutta
Scientific Workers' Forum, West Bengal
Sramajibi Samhati Samity
Sunday Sitting, Bansberia
W. B. Voluntary Health Association

The list is very much incomplete, we know, helplessly.

Individuals actively contributing to the cause are numerous. The contribution of the district newspapers and periodicals for the campaign is acknowledged. We appreciate the efforts of the organisations who joined protest demonstration and procession of the Forum on 2nd September '84. □

The World of Drugs

—issues and tasks

1. The practice of using drugs to save a life, cure ailments and prevent diseases is as old as human civilization. Treatment with drugs is an important and integral part of the total health care system. The need of drugs is so vital that often we are lured to accept anything that poses as 'drug' without thinking rationally. As such, since ancient times man has repeatedly been cheated by imposters where use of drug is concerned. But when modern medicine started to explain the physiology of the body, causes of diseases and methods of treatment and prevention with rational arguments and evidences and thus placed the subject of health-disease-treatment on a scientific basis, obviously those items which gained recognition as drugs had to fulfil all scientific scrutiny regarding their efficacy. People gained the confidence that whatever might be the hazards in the various unscientific systems of treatment, at least where modern medicine is concerned, there would be no scope for doubt regarding efficiency and credibility of drugs.

2. Presently, that conviction has received a jolt. The chaotic state of affairs in the field of drugs used in modern medicine, where the lust for profit-making has often resulted in unscientific unethical and dangerous practices while marketing drugs, is a real threat to mankind. Yet very few people in our country are aware of such a dangerous situation.

3. Essential drugs

In India, due to non-availability of drugs, millions die prematurely and many more become crippled. Every year about 5,00,000 people die from tuberculosis, 1.5 million succumb to enteric diseases, 40,000 children become blind due to lack of Vitamin A. It may also be mentioned that one-third of the leprosy cases of the world belong to Free-India. All these deaths and infirmities are preventable if treated properly, but most of the patients have no access to treatment or drugs. The drugs which are required for the treatment of the prevalent diseases of a country are called 'Essential drugs'. The Hathi committee set up by the Govt. of India in 1975 and the World Health Organisation in 1977 has compiled a list of such 'Essential drugs' and has recommended that these be made available for all. Govt. of India is committed to implement the WHO declaration of "Health for all by the year 2000". Making essential drugs available to all in sufficient quantities, is one of the pre-requisites for translating the call into practice. Government of India has done nothing in this respect and has not even prepared a list of "Essential drugs" as a first step. Experts have pointed out that India has the necessary raw materials, technical knowhow and infrastructure to produce sufficient quantities of essential drugs within the country. Govt. of India very reluctantly named 360 drugs as

essential ones and fixed the margin of profit (45—55%) on these drugs, while unlimited margin of profit has been allowed in case of others which vary from 100% to infinity. This has resulted in scarcity of essential drugs in our country while the non-essential ones flood the market. Very recently a committee appointed by the Govt. has recommended that except in case of 95 drugs, all other drugs be exempted from price control. It appears that Govt. thinks that to make essential drugs available in sufficient quantities, there is no otherway but to allow unlimited profit. But it is strange that the low purchasing capacity of the masses escaped its attention.

4. Non-essential drugs

Which drugs may be termed as non-essential? Various categories of drugs fall under this groups—

a. Various vitamin preparations, tonics, drugs for cough & cold, digestives, drugs to increase vitality, growth promoting "Foods", anabolic drugs for children etc. which are sold over-the-counter as drugs, and which have no rational or scientific basis—are not regarded as drugs in the real sense of the term in medicine.

b. Various ingredients are often combined together at random without any scientific basis and are marketed as new drugs—these are not only non-essential but often harmful too.

c. Various drugs which have been banned in developed countries as harmful ones or which are used under strict vigilance in selected cases, e. g. EP forte, Phenyl butazone, Analgin, etc.

are being sold freely in this country.

d. Some drugs whose use in cases of children have been banned in other countries are being recommended for the very children here e. g. Anabolic steroid, Lomotil, Tetracycline etc.

5. Profit

All these dangerous practices against humanity are being perpetrated with the sole motive of profit & more profit. Since the Forties, when many life-saving drugs were discovered, the demand for these drugs spread world wide. People believe that when scientists discover a new drug—the drug companies manufacture and market them in the interests of the patients and for the good of mankind. But the bitter truth is that in capitalist economy everything is produced and sold as a commodity and drug is also treated as such. As a result profit is the sole motive here. Here are some of the examples—

a. A company which markets a new drug has the sole patent on it and is allowed to fix the price on its own whim for 5 years.

b. Markets are often created for the non-essential drugs through the media of advertisement & canvassing e. g. vitamins, tonics, etc.

c. High rates of commission are given to chemists for increased sale. In other words, if he can sale the drug without taking into account whether the same is required for the patient or not, or if he can sale it by misleading the unwary ones, that person will get more commission. In this connection it should be mentioned that about 48% of drugs are sold in our country

over-the-counter—without doctor's prescription. A joint survey of Government & non-Government teams in Andhra Pradesh has revealed this sorry state of affairs.

d. Spurious preparations are also prevalent in the drug market. Survey by the Government has revealed that 18% of the drugs in the market are substandard and more than half of these are marketed by famous multinational drug companies.

The main profit of the multinationals however, come from manipulation of the international price. On the plea of maintaining the standard of the drugs these companies buy raw materials and bulk drugs not from international market but from their head offices in foreign countries. Head office supply a drug at say, Rs. 5,000 whose real price might be Rs. 100. There is no control on this regard. Cases are on record where the head office does not manufacture the drugs but buy it from international market at Rs. 100 & sale it to its Indian unit for Rs. 5,000. The Indian unit markets the drug showing profit at the controlled rate over purchasing price of Rs. 5,000. That means the profit, remains marginal in papers, but in reality Rs. 4,900 is being siphoned away to foreign countries for a drug whose real price is Rs. 100 only. This is not profit making but sheer fraud, to say the least. Such fraud is continuing in regard to several drugs. Recently, in the case of a drug—rifampicin, fraud of about Rs. 3 crores has been unearthed but Govt. has not as yet been able to recover it from that

company.

6.Brand Name

With an eye to this excessive profit, brand names for drugs have been introduced. Same drug is being marketed by 25 different companies under 25 different brand names. The drug is the same, but the marketed names and prices vary. For using these brand names the companies have to pay 12.5% extra tax. Over and above this, there is also expenses for advertisement, canvassing & token gifts to medical practitioners in order to push that particular brand in the market. And the poor consumer has to foot the bill for the entire additional expenditure. No wonder that although there are about 300-400 varieties of basic drugs, brand names of drugs in the market number about 45,000.

7. Considering the helplessness of the patients from different aspects one question pops up repeatedly. The patients buy a drug on the advise of the doctors at least in 52% of cases. Why do then doctors prescribe the non-essential & often harmful drugs? Though unbelievable, yet it is true that doctors have no access to any information regarding the scientific or commercial aspects of drug in our country. Last year in the month of July, 1983, Govt. of India banned 25 categories of drugs—but not even 2% of the doctors are aware of this fact. On the other hand, the drug companies are flooding the doctors with thousands of informations regarding their products through glossy publications & resourceful sales representatives.

The doctors depend mainly on the informations thus received. It has been revealed through various surveys that drug companies not only suppress unpalatable facts regarding their products but also publish false datas for circulation. We have to face the bitter truth—medical care & drug are treated as commodities in our country. Practising doctors sell their expertise in order to earn livelihood which is bought by the affluent section of the society. Due to propaganda from various sources the consumers have acquired such a false & unscientific notion that they always demand instant result and the doctors, in order to satisfy their clients, take help of the unscientific remedies in order to show instant result. This dangerous culture has vitiated the situation to such an extent that the patients themselves often order the vitamins, tonics & such drugs & demand prescription from doctors for the same and get it. The exception to this prevalent trend is encountered only in hospitals where commercial interest and the urge to earn livelihood by satisfying the client do not dominate and as such the practice of unscientific treatment is least. The medical education itself is also faulty. Though the medical students are taught only generic names, there is no scope for them to learn about the drug industry, commercialisation of drugs, drug pricing & unscientific methods of treatment prevalent in our country.

There is very little scope here for research on the efficacy & side effects of drugs. Little research that carried out here are funded by the

drug companies. Needless to say the findings become heavily biased in favour of the companies. Very few of the reports of harmful drugs published in foreign countries reach us. The drug companies try their level best to denounce those reports and utilise the services of some of the famous practitioners in this endeavour. To sum up—medical treatment is considered in our country as a saleable commodity and people associated with this system are partners in this mercenary culture. We have no machinery to monitor the effects of new drugs on human body & there are several instances where experiments with unknown drugs were carried out on people without their knowledge and consent.

8. It must however be admitted that in modern medicine there is still some vigilance (though meagre) over harmful effects of drugs, their misuse, profit mongering, etc. & there is a constant effort to curb all these malpractices. It is also reassuring that a section of the doctors have come forward to expose the chaos & unethical practices prevalent in the field of medical treatment & are trying to cleanse the Augean stable. Associations of sales representatives of the drug companies are also trying to expose the misdeeds of the multinationals.

But in the field of other modes of treatment like Homeopathy, Ayurved, Unani etc. where various items are sold as drugs—there is no methodology of checking their efficacy & usage. A dangerous trend is being discernible at present. The Government is reluctant to provide primary

health care and essential drugs for the masses but the demand from the public is increasing. As a result the Government has launched a campaign hailing the ancient glory of Ayurved and traditional remedies to create an impression that these remedies are best suited for the villagers.

We are afraid that such an attitude will only embolden others to pass off anything & everything as drug. We want to state categorically — a drug, to whichever system it might belong, must satisfy certain established definite scientific criteria to obtain license as drug and allowed to be marketed.

9. Certain drugs which are banned in U.S.A. are not allowed to be manufactured there also. Recently, there is a move in U.S.A. to enact a bill which will permit a company to manufacture those banned drugs in that country for export purposes only. Due to laxity in drug control everything can be sold as drug in the third world countries and because the level of profit is sky-high, so one easily guess the motive behind this move. On the other hand, whatever little restrictions the Govt. imposed on the multinationals in our country, are being withdrawn in lieu of reduction of foreign equity share to 40% of the total. Quite expectedly the companies have agreed eagerly to implement this change. Recommendations of a recent Govt. committee is still more disappointing. They have recommended that price control should be waived in case of all but 95 so called essential & life saving drugs.

It is very clear to us that where the question of life & death of the people are concerned such chaos & unscrupulous practice should not be allowed to continue. Everyone of us has some responsibility in this regard. As remedial measures—

We Demand

I. Government must identify life saving & essential drugs, must ensure their availability in sufficient quantity & steady supply to all those who need it. Those who have no purchasing capacity ought to get it free.

II. All the non-essential & unnecessary drugs must be banned. Only those drugs which will stand the test of scientific scrutiny, will be given licence as drugs. Where relatively safer alternatives are available, the potentially harmful drugs must be banned. Where there is no safer alternative, the use of those risky drugs must be strictly controlled. Those drugs which are banned in other countries, must not be manufactured or imported in this country, except for the purpose of research and test. On the basis of the recommendations of Hathi committee the system of drug control must be strengthened at all levels.

III. The malpractices in drug pricing must be stopped. Brand names of drugs must be replaced by generic names. There should be no tax on essential drugs. To control the price of drugs, all the raw materials & bulk drugs should be imported from international market at competitive prices through trading corporation.

IV. Except scientific facts, nothing should be advertised regarding drugs. Government must take the responsibility of supplying all the scientific data to the doctors regularly.

V Stringent penal measures must be enacted against manufacture & sale of banned drugs.

VI. There should be social control over the drug industry & drug trade.

11. To realise the above mentioned demands we are taking following steps —

I. The first booklet of Drug Action Forum is to be distributed at all levels. The second booklet to be published by the Forum will contain detailed accounts of various non-essential, harmful and banned drugs.

II. Various mass organisations, women's organisations, social service organisations, science movements associations etc. should be involved in this movement.

III. In all public gathering, meeting etc.

the objectives of the forum is to be propagated through posters, leaflets & booklets.

IV. For the doctors—a bulletin containing scientific informations regarding drug treatment should be published regularly.

V. Steps to be taken to publish drug informations through mass media.

VI Public meetings, seminars & discussions must be organised regularly.

VII Special efforts should be made to propagate the idea among the political parties & trade unions.

VIII. Demands to be placed in an organised way before the State Govt. & Drug control authorities to take proper steps and a movement is to be organised.

IX. Everyone will be made aware of the various activities & steps taken by the 'All India Drug Action Network.'

DRUG ACTION FORUM

15.11.84

West Bengal

● List of Relevant Books & Periodicals

1. Aspects of Drug Industry in India
—M. Bhagat,
Centre for Education & Documentation
2. Bitter Pills—Diana Melrose, Oxfam, U K.
3. Prescription For Change
4. All India Drug Action Network Newsletter
—VHAI, New Delhi
5. Pune Journal of Continuing Health Education—1913 Sadashiv Peth,
Pune 411 030
6. HAI Newsletter—HAI, Penang,
Post Box 1045, Malaysia

7. Masik Ganaswasthaya—Ganaswasthaya
Kendra, Dhaka, Bangladesh
8. Drugs and the Third world—Anil Agarwal
9. Who needs the Drug Companies
—Haslemir Group.
10. The Other Part of the Story
—J. S. Mazumder

Membership of Drug Action Forum, W.B.

| | Annual | Life |
|------------------------------|-----------|------------|
| Individual | Rs. 10.00 | Rs. 100.00 |
| Institution/ Organisation | Rs. 25.00 | Rs. 250.00 |

Glimpses of the World of Drugs

Third World

□ Out of 87 diseases specific to poor countries, there are vaccination for 10 and Satisfactory drug treatment for 23. But no drug at all to treat 32 diseases and the remaining 22 can only be treated with very unsatisfactory drugs that have serious side-effects.

□ All the money spent on public health services in 67 of the poorest countries adds up to less than the rich countries spend on tranquilizers alone.

□ Philippines, where in 1980, 42 million pesos were spent on 'Vicks Vaporub' an 'useless medicine', by comparison only 4.1 million pesos were spent on the treatment of malaria, and the 20,000 leprosy patients received only 2.15 lakh pesos to treat this illness.

□ 18% of the drugs imported in North Yemen in 1980 were vitamins and tonics compared to only 1% for drugs to treat the country's three most widespread diseases e.g. Malaria, Bilharzia, TB.

□ In Nepal in '80—more than 1/3 of all drugs on the market were tonics.

□ In Bangladesh (before the promulgation of drug policy)—25% of drugs expenditure were on vitamins.

□ In Nigeria 49% of drugs expenditure is for over-the-counter products of doubtful therapeutic value.

□ Anabolic Steroids are a group of drugs

marketed and promoted by Organon as growth stimulator in children, appetizer, in malnutrition etc. Scientific scrutiny has revealed that these drugs cause stunting of growth, voice change in women and even sex change. In fact these drugs should never be used for children and for adults, there is only one or two disease where these could be used by only specialist doctors.

WEMOS, a dutch social action group, filed a case against Organon in a Netherland court accusing Organon of practising a dual standard i.e. strictly following the scientific limitations in publicity in the developed countries but indulging in unrestrained false propaganda in the third world countries including India. The court ordered Organon to use same labelling and medical information in all countries and Organon accepted the verdict and said that they stopped practising this type of double standards in propaganda. WEMOS then exposed with proof that in Peru Organon still published the false and exaggerated claims regarding the efficacy of the drugs. Confronted with this, Organon revised their claim. Actually the double standard is still being practiced.

□ "We cannot afford to provide facilities for a few people to get advanced treatment for special heart diseases while the masses of our people are not able to get treatment for common diseases which make their life a misery. This is a hard doctrine, but it is a question of

priorities. To plan is to choose,"

—Julius K. Nyerere, President of Tanzania

Other Worlds

□ Govt. enquiries report i.e., Sainsbury report (U.K.) of '67 showed that out of 2241 products—35% were ineffective, obsolete or irrational combinations.

□ F.D.A. (USA) from their studies in '71 found that out of 2000 drugs—1200 fails to justify their therapeutic claims.

□ Enterovioform & Mexaform are drugs marketed by Ciba-Geigy company against diarrhoea (also marketed by other companies e.g. Entero-quinol, Dequinol, Amicline, Nivembin, Disdoquin, Diogyl, Resotren Comp etc). This drug often causes blindness and paralysis of the legs. In Sweden, when the Ciba-Geigy refused to stop marketing of these drugs, the Swedish Doctors began a boycott of all drugs of Ciba-Geigy from 1977 which caused a drop of 25% of sale of drugs of the company. At last, Ciba-Geigy stopped sale of these drugs since October, 1982 in some 90 countries and recently announced that they are abandoning their world-wide supply of Enterovioform and related drugs by the end of March, 1985.

Will the other companies follow the example of Ciba-Geigy ?

Ref : HAI News, No-1, I.O.C.U. press release, 30.11.84

□ A report says that 45 million pounds spent on vitamins in the U.K. during '83 was a waste of money and a potential health hazard.

□ A survey of casualty wards at 20 hospitals in '82 (in UK) showed one in every 1000 patient was brought in having taken over doses of vitamin pills. Many of them were children.

□ As far back as '78 the member states gave the W.H.O. a mandate to start work on an international code of drug marketing practices. But U.S.A. vehemently opposed to such action. U.K. argued that attempts at self-regulation by industry should be tried out before preparing such marketing code. (U.S.A. provide 1/4 of the total W.H.O. budget) But in May '84 some developing and developed countries backed the need for unbiased drug information and better marketing practices called for in a resolution i. e. 'Rational use of drugs'. This time though U.S.A played the same role some European countries like U.K. and Netherlands agreed to a proposal that a meeting of experts be held

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in 1985 to look into marketing practices and report to the 1986 World Health Assembly. This time Japan and West Germany abstained from voting. U. K. voted in favour of the resolution with other 100 member states of W.H.O. But the financial support for this programme was not satisfactory.

□ From April '85 Doctors of National Health Service (U. K.) will prescribe some medicines in generic name. This banning of trade names will reduce Britain's annual drug bill by nearly 100 million pounds. The restrictions will apply to all cough and cold remedies, tonics, indigestion tablets, headache pills and minor pain killers, vitamin pills, laxatives, sedatives and sleeping pills.

Ref: Guardian, 9.11.84

□ Presidential decree, signed on 23.2.84 will provide Mexicans with cheaper and effective medicines and will strengthen national drug industry. Though in '78 they had introduced a list of 426 generic drugs, comprising 614 preparations but it was compulsory only for those who were prescribing medicines under social security scheme. Now it will be mandatory for the entire public sector in Mexico. Not

only that this new rule has forced the producers to write generic name on the foil with exactly the same character as the brand name and that must be completed by Aug '84, the pharmaceutical policy will reduce prices on 26 top priority pharmaceuticals by 20% and will establish a single price for similar products from different manufacturers. It is estimated that this measure alone will save Mexico about 105 million US dollar per year in foreign exchange.

Ref: Health Now, No.-4, 14.5.84

In India

□ "Drug manufacture has become a powerful industry, subject to the same driving considerations of other big industries, that is, concentration on profits, fierce competition and recourse to hard-sell advertising. Medicines which may be of utmost value to poorer countries can be bought by us only at exorbitant prices. This apart, sometimes dangerous new drugs are tried out on populations of weaker countries although their use is prohibited within the countries of manufacturer."

—Indira Gandhi in her keynote address as the guest speaker in the annual assembly of WHO, 1981.

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□ In a litigation against the reluctance of the Govt of India to ban the harmful drug, the Hon'ble High Court of Kerala said in its judgement—

“As between the lives of the citizens of this country on the one hand and the loss that may result to the manufacturers and traders by the immediate ban on the manufacture and sale on the other, the Government has chosen to view the latter as of more concern...while it is necessary that the manufacturer and the trader must not loose in his industry or business, the insurance against the loss should not be at the cost of human life or human health.”

Regarding the dangerous drug Amidopyrine the judgement said, “Even though Government of India had realised as early as in February, 1981 of the danger of the use of this drug consequent on which its import and manufacture had been banned in India, the Government seems to have been powerless in effectively enforcing this ban...”

On the banning of a drug, the judgement said, “The overriding consideration must be the lives and health of the consumer public.”

□ The Government has issued notices to some 50 drug companies for recovery of ‘unintended’ profits, running into several crores of rupees, made by them from the marketing of formulations based on certain vital bulk drugs. These recoveries are to be made with retrospective effect from 1979 when the Drug Prices Control Order (DPCO) was brought into effect. The ‘unintended’ profits are the profits in excess of what the law allows under the DPCO. The companies have been directed to deposit the amounts with the Drug Prices Equalisation Account as per the provisions of the DPCO.

...

The larger Indian drug companies and the multinationals have been accused time and again of circumventing the provisions of the DPCO and earning excess profits. The recent order on 50 drug companies to deposit the excess profits earned by them has dramatically brought home the truth of the charge. However, reports indicate that the drug companies are not likely to comply with the government order...

Ref : Economic and Political Weekly, 8.9.84

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● Names of some Drug Action Groups

1. Ganaswasthya Kendra—Savar
P.O. Nayarhat, Dhaka, Bangladesh.
2. Health Action International (HAI)
Ms. G. S. Foo, Pharmaceutical Action
Project IOCU Regional Office for Asia &
Pacific.
3. Medico Friend Circle, 326, 5th Main,
1st Block, Koramnagala, Bangalore—560 034
4. Wemos-Ninahassa Str—1
Amsterdam, Holland.
5. Black Health Workers and Patients group
C/o Camden Community Law Centre,
146, Kentish Town Road, London NW1
6. Politics of Health group
C/o BSSRS, 9, Poland Street, London WI,
7. OXFAM—274, Ranbury Road,
Oxford OX 2, 7 DZ.
8. IOCU—Post Box 1045, Penang,
Malayasia
9. Centre for the progress of Peoples
48 Princess Margaret Street
Kowloon, Hongkong.
10. Arogya Dakshata Mondal, 1913 Sadashiva
Peth, Pune 411 030, Maharashtra.
11. Voluntary Health Association of India
C-14, Community Centre, S.D.A.
New Delhi 110 016.
12. Kerala Sastra Sahitya Parisat,
Parisat Bhawan, Trivandram 695 037
Kerala.

The American Story

Not being content with the sky-high profit from selling unscientific, unnecessary and harmful drugs in the third world countries, the American Drug Companies now intend to sell 'banned drugs' for more and more profit. At present, the US drug companies are not permitted to manufacture in USA drugs not approved for sale in USA. Recently, a bill has been introduced in the US senate which, if enacted, will authorise the US drug companies to manu-

facture these 'banned drugs' for EXPORT ONLY.

Drug Action Forum, W.B., alongwith Indian Medical Association—Bengal State Branch, Health Services Association, W.B. and All Bengal Junior Doctors Federation protested to the US President, Ronald Reagan against this inhuman act and received a very unsatisfactory response from the appropriate authority. The Forum sent a rejoinder and all these documents are reproduced below to tell their own story.

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COMMUNITY HEALTH CELL
47/1, (First Floor) St. Marks Road,
Bangalore - 560 001.

Mr. Ronald Reagan,
President, United States of America,
Washington D. C., U. S. A.

1st September, 1984
Calcutta.

Dear Mr. President,

We beg to draw your kind attention to a bill (No. 52878) which, we understand, is ready to be introduced in the U. S. Senate. The bill, if passed by the Senate, will permit the pharmaceutical companies of your country to manufacture drugs, NOT APPROVED FOR SALE IN U. S. A., for the sole purpose of exporting (those harmful and injurious drugs) to third World countries.

In the past, even in absence of encouragement from the U. S. Government, many multi-national companies with head quarters in U. S. A., have utilised the third World countries either as a market for selling substandard and dangerous drugs (disapproved for sale in U. S. A.) at higher prices or to use those countries as field laboratories for trial of new but dangerous drugs, without slightest consideration of their possible ill effects on human lives.

You have reiterated time and again America's intention of upholding human rights whenever and whenever necessary. If the purported bill is allowed to be enacted into a law, it will, in effect, legalise murder of the common and innocent people by the American drug manufacturers in the third World countries. Mr. President, do you not consider it a flagrant violation of human rights?

We are confident that, you, as the Head of one of the largest democracies of the World, shall not allow the human lives in the third World countries to be endangered merely for financial gain of a few drug manufacturers of your country. We, on behalf of the Indian people, implore you to stop the bill before it is too late

We earnestly await your reply. With kindest regards,

Your sincerely,

Dr. S. C. Chakraborty, President,
Health Services Association, W. B.
25, Dixon Lane, Calcutta 700 014

Dr. S. B. Chakravorty, President,
Indian Medical Association
Bengal State Branch,
67, Lenin Sarani, Calcutta 700 013

Dr. Parimal Halder, President,
All Bengal Junior Doctors'
Federation, Kitchen Block,
R. G. Kar Medical College,
1, Khudiram Bose Sarani,
Calcutta 700 004

Dr. Arun Sen, President,
Drug Action Forum, S/3/5,
Sector III, Salt Lake,
Calcutta 700 064

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Nov. 6 1984

Dr. Arun Sen

President

Drug Action Forum, S/3/5

Sector III, Salt Lake

Calcutta 700 064

INDIA

Dear Dr. Arun Sen :

Your September 1 letter regarding proposed drug export legislation addressed to the President of the United States was forwarded to my office for consideration and reply.

As Commissioner of Food and Drugs, I am well aware of the health issues involved in the export of unapproved drugs to less developed countries. Under existing U. S. legislation, commercial shipments of unapproved new drugs are not allowed, either for domestic or export markets. I can assure you that, under the proposed U. S. legislation, sufficient safeguards will continue to exist to prevent export shipments of banned or otherwise unsafe or ineffective products.

The proposed amendments to the U. S. Food, Drug, and Cosmetic Act which were before the Congress had eight conditions which an unapproved new drug would have to meet before it could be exported. These include :

- The drug must not be banned as unsafe or ineffective in the United States or in another country. If it has been banned, the Secretary of the Department of Health and Human Services must determine that it will be useful for particular conditions or diseases in the requesting country that do not exist in the country in which it is banned.
- The drug must not be in conflict with the laws of the country to which it is intended for export.
- A notice of intent to export the drug must be submitted to the federal government at least 60 days before the first export to each country.

Under the 1976 medical device amendments, the Food and Drug Administration has permitted the export of unapproved medical devices using similar pre-export requirements. In our years of experience with this system, we have found no evidence that these exports pose any hazard to people in countries importing these devices.

We strongly believe that the proposed drug export amendment has adequate safeguards to prevent shipment of harmful or dangerous drugs to other countries. While the proposed drug amendment discussed above did not pass in the recently completed 98th Congress, we expect further consideration of this issue in the next Congress.

Thank you for bringing your views to our attention. Please let us know if we can be of further assistance.

Sincerely yours,

Frank E. Young, M. D., Ph. D.
Commissioner of Food and Drugs

Dated, the 9th January, 1985.

To

Frank E. Young, M. D., Ph. D.
Commissioner of Food & Drugs
Department of Health & Human Services, USA
Food & Drug Administration
Rockville MD 20857 USA.

Dear Dr. Frank E. Young,

Thank you for your reply dated November 6, 1984 to our observations on the proposed US bill for manufacture and export of drugs not approved for sale in US. The most important safety measure that you have mentioned to have been incorporated in the proposed legislation is confusing, if not inexplicable. Let us quote it—"The drug must not be banned as unsafe or ineffective in the United States or another country. If it has been banned, the Secretary of the Department of Health & Human Services must determine that it will be useful for particular conditions or diseases in the requesting country that do not exist in the country in which it is banned."

We want to know the grounds, other than unsafe and 'ineffective', the drugs in the US had been or could be banned on. Further, we want to know the names of diseases prevailing in a country like ours but non-existent in the US and the names of the drugs banned in the US but useful in those diseases.

We understand that your Government depends on the functioning of an adequate governmental drug approval authority and it is surprising that you are not aware of the fact that the standard of functioning and resources of the Drug Control Authorities in the

third world countries including ours is terribly low and below the minimum desirable. While the trend of the international bodies is working towards tightening up of drug exports from developed to the developing countries, the objective of your proposed bill is not only undesirable but contrary to the international trend and will further aggravate an already dire situation.

While it is unbelievable that you are not informed of the inhuman malpractices the Trans National Drug Companies (TNCS) resort to in the third world countries in their promotion to create demand for irrational and harmful drugs and sale of those drugs at sky-high profit. Your proposed bill will further encourage the TNCS in their misdeeds. Instead, we would have been grateful, had your Government made an effort to help the third world countries in attaining self-sufficiency in the most urgently essential drugs.

May we further request you to please take the trouble of sending us a copy of the provisions of the regulations and acts regarding drugs, cosmetics and food materials.

Awaiting an early response,

Yours faithfully,

Dr. Arun Sen

Chairman

DRUG ACTION FORUM, WEST BENGAL.

Copy forwarded to :

(i) Senator Orrin Hatch & (ii) Senator Edward Kennedy ; US Senate, Washington, DC 20510 USA.

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Composition:

Tablets containing 2 mg. Ethylestrenol.

Drops containing 2 mg. Ethylestrenol per ml. aqueous solution.

Clinical Effects:

Ethylestrenol, the active principle of ORABOLIN, is a powerful anabolic agent which is fully effective when orally administered. Extensive tests have shown that ethylestrenol has an anabolic/androgenic ratio almost 20 times than that of methyltestosterone. In practice the small daily dose required, 0.05 mg. per Kg. body weight, ensures that the only clinical effect is anabolism.

ORABOLIN stimulates the appetite, promotes weight gain and in elderly debilitated patients produces a marked psychological improvement. Metabolic balance studies have shown that both nitrogen and calcium are retained during treatment, and that a negative nitrogen balance during corticosteroid therapy can be reversed. ORABOLIN is exceptionally well tolerated, causes no fluid retention and is free from harmful effects on liver and adrenals.

The raspberry flavoured liquid administered in drops is especially meant for younger children and infants.

Indication:

In adults:- Convalescence, weight loss, debility, osteoporosis, slow-healing fractures, during corticoid therapy, as an adjuvant after acute and chronic diseases.

In Children:- Retarded growth, lack of appetite and insufficient weight, nutritional disorders, failure to thrive and after infectious diseases.

Dosage:

Adults:- 2 tablets daily

Children:- According to body weight

| Weight in Kg. | Drops per day |
|------------------|---------------|
| Less than 10 kg. | 5 drops |
| 10-30 Kg. | 1 drop/kg. |
| more than 30 kg. | 30 drops. |

Packing:

Bottles of 20 tablets.

Dropper-bottles of 5 ml.

ORABOLIN*

Presentation Ethylestrenol Tablets Round, flat white tablets, diameter 9 mm, code marked 'SB3' on one side, with 'Organon' and star on the reverse side.

Active ingredient Ethylestrenol BP 2 mg per tablet.

Uses Ethylestrenol is an anabolic agent, the nitrogen and calcium retaining effects of which are fully effective when it is administered orally.

Dosage and administration Adults: 1-2 tablets orally daily. Not recommended for children

Contra-indications, warnings, etc Contra-indicated in pregnancy, prostatic carcinoma, breast carcinoma in the male and in severe disturbances of liver function.

Treatment should be discontinued if cholestatic jaundice appears or liver function tests become abnormal.

Tumours of the liver have been reported occasionally in patients subjected to prolonged treatment with C-17 α -alkylated androgenic-anabolic steroids. The possibility that these compounds may induce or enhance the development of hepatic tumours cannot at present be excluded and this should be considered when the use of this product is proposed, especially in young people who are not suffering from life-threatening disorders.

Patients with myocardial or renal dysfunction, hypertension or epilepsy should be observed carefully, since anabolic steroids may cause fluid retention.

Skeletal maturation should be followed carefully when treating young people, since anabolic steroids in high dosages may accelerate this process.

Caution should be observed in young women whose cycles are not yet stabilised.

In diabetics, the need for insulin or other anti-diabetic drugs may be reduced.

When administered in the recommended dosages and for short periods of time (up to four weeks) side-effects may occur very rarely. Occasionally after high dosages, some liver function tests show abnormal values. These deviations, however, are transient and completely reversible after discontinuation of treatment. In some cases, particularly those treated with high dosages, nausea and some water retention may occur.

The possibility of menstrual disturbances exists, probably resulting from an inhibition of the secretion of gonadotrophins from the pituitary and/or from the occurrence of a progestational effect. In such cases the treatment should be discontinued or the dosage decreased.

Pharmaceutical precautions Protect from light.

Legal category POM

Package quantities Bottles of 100 tablets

Further information Nil

Product licence number 0065/5043

Conflicting information on prescribing for children. Left, therapeutic information, Bangladesh ; right, entry data sheet for British Doctors.

☐ From 'Bitter Pills' by Diana Melrose

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Drug For The People

Or

People For The Drug

Drug Action Forum Calls upon all organisations and responsible individuals :

- Read and circulate the publications of the Forum.
- Organise meeting/seminar on drugs. Representative of the forum will attend the meeting, if informed.
- Arrange for publication of the excerpts from the booklet (মানুষের জন্ত ওষুধ, না ওষুধের জন্ত মানুষ) of the Forum in the local newspapers and periodicals.
- Attend every assembly of people in your area with the booklet and posters of the Forum.
- Involve the Students community with the objects of the Forum.
- Get in touch with the Forum in all matters involving Drugs.

To correspond :

Dr. Sujit K. Das

Convener,

Drug Action Forum, W.B.

S/3/5, Srabani, Sector-III,

Salt Lake, Calcutta : 700 064

drug action forum, w.b. demands

- self sufficiency of the country
in essential drugs
- removal of
useless, unscientific and harmful drugs
- ban the 'banned drugs'
- reduce drug prices
- abolish brand names
- introduce mandatory generic names
- social control
over drug industry and trade

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